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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,301	12/06/2006	Kenji Nakanishi	64353(70904)	6578

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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,301	NAKANISHI ET AL.	
	Examiner	Art Unit	
	PAUL C. MARTIN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-18* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 and 14-18 are pending in this application, Claims 1-10 and 14-17 are acknowledged as withdrawn, Claims 11, 12 and 18 were examined on their merits.

The objection to Claim 11 (referenced Claim 1 by mistake) for minor informalities has been withdrawn due to the Applicant's amendments to the Claims filed 03/19/09.

The rejection of Claims 11 and 12 under 35 U.S.C. § 112, 1st paragraph, as failing to comply with the enablement requirement, has been withdrawn due to the Applicant's amendments to the Claims filed 03/19/09.

The rejection of pending Claims 11 and 12 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been withdrawn due to the Applicant's amendments to the Claims filed 03/19/09.

The rejection of Claims 11 and 12 under 35 U.S.C. § 102(b) as being anticipated by White *et al.* (1980) has been withdrawn due to the Applicant's amendments to the Claims filed 03/19/09.

The rejection of pending Claims 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over White *et al.* (1980) in view of Tsai *et al.* (2003) has been withdrawn in view of the perfection of Priority by filing of a certified translation of Japanese Application 2003-120630 filed on 04/24/2003, which is sufficient to remove Tsai *et al.* (2003) as a reference.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 03/20/09 was filed after the mailing date of the Non-Final Office Action on 01/05/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's arguments, see Remarks, filed 03/19/09, with respect to the rejection(s) of claim(s) 11-13 under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of White *et al.* (1980) in view of Proksch *et al.* (1996).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 12 and 18 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over White *et al.* (1980) in view of Proksch *et al.* (1996).

White *et al.* teach a method wherein a vigorous inflammatory reaction is induced by applying *S. aureus* Protein A to the skin of human subjects, wherein the skin stratum corneum has been partially removed by tape stripping (Pg. 43, Lines 20-21 and Pg. 44, Lines 1-9 and 19-26).

White *et al.* does not teach wherein when Protein A is applied on the skin of a model organism, SDS is also applied.

Proksch *et al.* teaches wherein tape stripping and sodium dodecyl sulfate (SDS) are used as methods of permeability barrier (skin) disruption in human subjects (Pg. 631, Column 1, Lines 23-31) and that it was well known in the art that irritant contact dermatitis often precedes allergic contact dermatitis (such as AD) (Pg. 631, Column 1, Lines 16-18).

It is inherent in the combined method of White *et al.* and Proksch *et al.* that the inflammatory skin lesions formed would be atopic dermatitis-like and/or Atopic Dermatitis as the Specification defines an "inflammatory skin lesion like AD (atopic dermatitis) as any immune disease which develop dependently on IL-18 and whose main symptom is inflammation on skin, and is not limited to pruritic chronic inflammation which is strictly discerned as AD (Specification, Pg. 12, Lines 8-12). As the combined method of White *et al.* and Proksch *et al.* results in a symptom of inflammation of the skin and performs every claimed method step with the same components, it inherently meets the claim limitation.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of White *et al.* for inducing a vigorous inflammatory reaction by applying *S. aureus* Protein A to the tape stripped skin of human subjects by using SDS as the means of disrupting skin because both tape stripping and SDS application were are art recognized techniques of disrupting skin for the purpose of generating an immune response.

The MPEP states:

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll* Co. *v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

04/07/09

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657